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Docket No.: 02521/100K106-US1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Fred Mermelstein, et al.

Application No.: 10/729,869

Confirmation No.:

Filed: December 5, 2003

Art Unit: N/A

For: NMDA RECEPTOR ANTAGONIST
FORMULATION WITH REDUCED
NEUROTOXICITY

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In compliance with the duty of disclosure under 37 CFR §§ 1.56 and 1.97, attached hereto is a copy of the Form PTO/SB/08. The copies¹ of the documents listed thereon have been made of record in parent application Serial No. 10/256,283 filed September 25, 2002. These documents contain information which the Examiner may consider to be important in deciding whether to allow the present application to issue as a patent.

In accordance with MPEP Sections 609 and 707.05(b) it is requested that each document cited (including any cited in applicants' specification which is not repeated on the attached Form PTO/SB/08) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO/SB/08, so that it will appear on the face of the patent issuing on the present application, even if the Examiner does not consider it sufficiently

¹ Copies of the cited references were submitted in parent application Serial No. 10/256,283 and are not submitted here pursuant to 37 CFR §1.98.

pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with.

The present Disclosure Statement is also being submitted in compliance with 37 CFR § 1.56 as an Examiner might consider any cited document important in deciding whether to allow the application to issue as a patent, but the citation of each document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR §§ 1.104(a) and 1.106(b), and in the course of such search will review for relevance every document cited on the attached form even if not initialed.

The Examiner is requested to consider the references referred hereto and initial the enclosed form PTO/SB/08 where indicated.

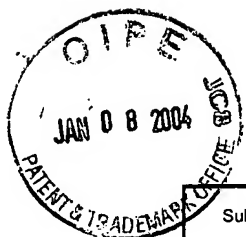
Early and favorable consideration is earnestly solicited.

Dated: January 8, 2004

Respectfully submitted,

By Sandra S. Lee
Sandra S. Lee

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PTO/SB/08a/b (06-03)

Approved for use through 07/31/2003. OMB 0651-0031

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| Substitute for form 1449A/B/PTO | | | | | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/729,869 |
| | | | | Filing Date | December 5, 2003 |
| | | | | First Named Inventor | Fred Mermelstein |
| | | | | Art Unit | N/A |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 2 | Attorney Docket Number | 02521/100K106-US1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| | 1. | US-5,543,434 | | Weg | |
| | 2. | US-6,248,789 | | Weg | |
| | 3. | US-5,654,281 | | Mayer | |
| | 4. | US-5,352,683 | | Mayer | |
| | 5. | US-5,834,465 | | Olney | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
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| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-----------------------|---|----------------|--|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² | |
| | 6. | Ahuja, Br. J. Anaesth. 1983, 55:991 | | |
| | 7. | Battacharya et al., Ann. Acad. Med. Singapore 1994, 23:456 | | |
| | 8. | Bookwalter, Plastic Surg. Nursing 1994, 14:43 | | |
| | 9. | Brock-Utne et al., S.A. Med. J. 1982, 20:440 | | |
| | 10. | Clark and Kalan, J. Pain Symptom. Manage. 1995, 10:310 | | |
| | 11. | Collingridge et al., The NMDA Receptor, Oxford University Press, 1994 | | |
| | 12. | Dich-Nielsen et al., Acta Anaesthesiol. Scand. 1992, 36:583 | | |
| | 13. | Eide et al. Pain 1994, 58:347 | | |
| | 14. | Errando et al. Reg. Anesth and Pain Med. 1999, 24:136 | | |
| | 15. | Fine,, J. Pain Symptom Manage. 1999, 17:296 | | |
| | 16. | Fix et al, Experimental Neurology 1993, 123:204-215 | | |
| | 17. | Fix et al., Toxicol. Pathol. 1996, 24:291-304 | | |

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|---|-----------------|--|
| {W:\02521\100k106us1\00112659.DOC [Barcode] } Examiner Signature | Date Considered | |
|---|-----------------|--|

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|-----|--|--|
| 18. | Foster et al., Nature 1987, 329:395-396 | |
| 19. | Gebhardt, Anaesthesist 1994, 43 (suppl.2):S34 | |
| 20. | Gurnani et al., Anaesth. Intens. Care 1996, 24:32 | |
| 21. | Hirlinger and Pfenninger, Anaesthsist 1987, 36:140 | |
| 22. | Humphries e al., J. Burn Care Rehabil. 1997, 18:34 | |
| 23. | Jevtovic-Todorovic et al., Brain Res 2001, 895:264 | |
| 24. | Karpinski et al., Pain 1997, 73:103 | |
| 25. | Kuboyama et al., J. Toxicol. Sci. 1997, 22:153 | |
| 26. | Lauretti et al., Anesthesiology 1999, 90:1528 | |
| 27. | Malinovsky et al., Anesthesiology 1991, 75:91 | |
| 28. | Malinovsky et al., Anesthesiology 1993, 78:109 | |
| 29. | Mathisen et al., Pain 1995, 61:215 | |
| 30. | Mayer et al., Trends in Pharmacol. Sci. 1990, 11:254-260 | |
| 31. | Mercadante et al., J. Pain Symptom Manage. 1995, 10:564 | |
| 32. | Naguib et al., Can. Anaesth. Soc. J. 1986, 33:16 | |
| 33. | Olney et al., Science 1989, 244:1360 | |
| 34. | Shahar et al., Neurochem. Res. 1989, 14:1017 | |
| 35. | Wlaz et al., Eur. J. Neurosci 1994; 6:1710-1719 | |
| 36. | Knox et al., Anaesth Intens Care 1995, 23:620-622 | |

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• Attorney Docket No.: 02521/100K106-US1

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